

## Actions Taken by FDA Center for Veterinary Medicine

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The following corrections or additions to the January 1999 list were made in August 1999

### New Approvals

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#### NADA Number: 140-951

Trade Name: Clinacox<sup>TM</sup>  
Ingredients: Diclazuril  
Sponsor: Schering-Plough Animal Health  
Approval Date: April 21, 1999  
Status: Over-the-counter  
Route: Oral  
Species: Broiler chickens  
Drug Form: Type A Medicated Article to make Type C medicated feed  
Concentration: 0.2%  
Indications: For the prevention of coccidiosis by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mitis* (*E. mivati*), and *E. maxima*.  
Tolerance: 21CFR 556.175: A tolerance of parent diclazuril are: 0.5 ppm in muscle, 3 ppm in liver, and 1 ppm in fat and skin. An Acceptable Daily Intake (ADI) of 25 micrograms per kilogram of body weight per day has been established.  
Withdrawal: None  
Patent Number: 4,631,278                      Expiration date: August 1, 2004  
Exclusivity: 5 years

21CFR 556.175 and 558.198

#### NADA Number: 141-152

Trade Name: Revolution<sup>TM</sup>  
Ingredients: Selamectin  
Sponsor: Pfizer, Inc.  
Approval Date: May 26, 1999  
Status: Prescription only  
Route: Topical  
Species: Dogs and cats  
Drug Form: Solution  
Concentration: 60 mg/mL or 120 mg/mL  
Indications: For the prevention and control of flea infestations (*Ctenocephalides felis*), prevention of heartworm disease caused by *Dirofilaria immitis*, and the treatment and control of ear mite (*Otodectes cynotis*) infestations in dogs and cats. Also for the treatment and control of sarcoptic mange (*Sarcoptes scabiei*) in dogs and the treatment of intestinal hookworm (*Ancylostoma tubaeforme*) and roundworm (*Toxocara cati*) infections in cats.  
Exclusivity: 5 years

21CFR 524.2098

**NADA Number: 141-151**

Trade Name:	Zeniquin™
Ingredients:	Marbofloxacin
Sponsor:	Pfizer, Inc.
Approval Date:	June 26, 1999
Status:	Prescription only
Route:	Oral
Species:	Dogs
Drug Form:	Tablet
Concentration:	25 mg, 50 mg, 100 mg, and 200 mg per tablet
Indications:	For the treatment of bacterial infections susceptible to marbofloxacin.
Patent Number:	4,801,584                      Expiration date: September 8, 2007 4,864,023                      September 8, 2007
Exclusivity:	5 years

21CFR 520.1310

## Correction of a Final Rule

The Final Rule published in the Federal Register of June 30, 1997 (62 FR 35075 through 35077), FDA published a document reflecting a change of sponsor of several new animal drug applications from Fermenta Animal Health Co. to Boehringer Ingelheim Vetmedica, Inc. (then known as Boehringer Ingelheim Animal Health, Inc.). The sections affected were: 520.445b, 520.2345d, and 558.15.